Attachment I K062597

SECTION II 510(k) SUMMARY AND CERTIFICATION

NOV - 3 2006

510(k) Summary

K062597

TenderFlow™ Pediatric Venous Return Cannula

Submitter Information:
This Premarket Notification is submitted by:

Christina L. Thomas
Telephone: 1-800-262-3304, Ext. 6278

This Premarket Notification is submitted on behalf of:

Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, Michigan 48103

Device Names:

Proprietary Name:	TenderFlow™ Pediatric Venous Return Cannula
Common Name:	Venous Return Cannula
Classification:	Venous Return Cannulae are classified as Class II devices

Predicate Device:
The TenderFlow™ Pediatric Venous Return Cannula is substantially equivalent in intended use, materials, design, technology, principles of operation, and performance to the (unmodified) Terumo L Series Pediatric Venous Return Cannula. This device was in commerce prior to May 1976 and is considered a pre-amendment device. The pre-amendment status of this device was claimed by C.R. Bard at the time. This device is legally marketed and has not been the subject of Premarket Notification 510(k) clearance.

Intended Use:
The TenderFlow™ Pediatric Venous Return Cannula is a surgically invasive device indicated for dual cannulation of the superior and inferior vena cava and single cannulation of the right atrium for venous drainage during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hours of use.

Principles of Operation and Technology:
The TenderFlow™ Pediatric Venous Return Cannula is used in open heart surgery. During open heart surgery blood is drained into a venous cannula just upstream of the heart, at the superior / inferior vena cava and right atrium. The cannula is connected to tubing that routes the blood to a heart / lung machine where the blood is pumped and oxygenated. The blood then continues through this perfusion circuit back to the outlet side of the heart (the patient's aorta), where the blood re-enters the patient's circulatory system via an arterial cannulae.

Design and Materials:
The design of the TenderFlow™ Pediatric Venous Return Cannula consists of a dip molded, wire reinforced, straight venous return cannula (single-stage) with thin walls, and good flow performance. A non-reinforced clamping site is provided adjacent to the flared connection site. The overall length of the cannula from end to end is 12 inches. The distal portion of the spring reinforced body steps up in size both in internal diameter and outside diameter to enhance flow performance. This step-up diameter is approximately three French sizes larger than the tip section. The step occurs distal to the insertion portion of the cannula at approximately 3 to 5.5 inches from the tip. The length of the step increases with the French size.
The tip is integral to the body, not spring reinforced and is stiffened sufficiently to resist kinking and/or collapse.

The generic materials used in the TenderFlow™ Pediatric Venous Return Cannula are polyvinyl chloride and stainless steel wire which provides spring reinforcement throughout the body of the cannula. Each cannula is printed with a medical grade white ink, pigment color Marabu TPL 970 CDT PN.

Performance Evaluations:
The performance of the TenderFlow™ Pediatric Venous Return Cannula is substantially equivalent to the performance of the predicate (unmodified) device. Pressure Drop testing and hemolysis testing were conducted to demonstrate equivalence in performance. The hemolysis testing compared the predicate unmodified 12 Fr. Cannula to the modified 8 Fr. Cannula. The testing proved better results for the modified 8 Fr. Cannula.
Additional testing was performed on the modified Pediatric Venous Return Cannula to demonstrate current conformance to current market place performance expectations. Those tests included:

- Connector attachment
- Clamp test
- Kink test
- Collapse test
- Tensile test
- Simulated use test
- Ship test
- Shelf Life test

All test results are available upon request.

Substantial Equivalence Comparison:
The TenderFlow™ Pediatric Venous Return Cannula is substantially equivalent to the predicate Terumo L Series Pediatric Venous Return Cannula device as follows:

Intended Use: The TenderFlow™ Pediatric Venous Return Cannula and the predicate (unmodified) Terumo L Series Pediatric Venous Return Cannula share the same intended uses. Both are indicated for venous drainage during bypass surgery for up to 6 hours of use.

Principles of Operation and Technology: Both the modified and unmodified pediatric cannulae are used in open heart surgery to drain the blood out of the superior and/or inferior vena cava as well as the right atrium portion of the heart. This blood is removed from the heart through the cannula into the perfusion circuit tubing which connects to the heart lung bypass machine.

Design and Materials: The design of the TenderFlow™ Pediatric Venous Return Cannula consists of a dip molded, wire reinforced, straight venous return cannula (single-stage) with thin walls, and good flow performance. A non-reinforced clamping site is provided adjacent to the flared connection site. The overall length of the cannula from end to end is 12 inches. The tip is integral to the body, and is not spring reinforced. The tip is stiffened sufficiently to resist kinking and/or collapse.

The shape and hole pattern of the modified pediatric cannula is similar to that of the predicate (unmodified) L Series Pediatric Venous Return Cannula. Both cannulae (modified and unmodified) are wire reinforced, have 8 blood flow exit ports on the sides, a rounded tip that is not spring reinforced and a non-wire reinforced flared connector site.

There are two major differences between the modified and unmodified devices is that the modified devices also have a blood flow exit port in the tip itself, aside from the blood flow exit ports on the sides. The other difference is that the distal portion of the spring reinforced body steps up in size both in internal diameter and outside diameter to enhance flow performance. This step-up diameter is approximately three French sizes larger than the tip section. The step occurs distal to the insertion portion of the cannula at approximately 3 to 5.5 inches from the tip. The length of the step increases with the French size.

The design and the materials of the (modified) and the (unmodified) L Series Pediatric Venous Return Cannula are essentially the same. Differences include the graduated steps in the tubing of the modified device vs. a straight cannula body in the unmodified predicate device. An optional angled version is offered for the modified device in addition to straight cannulae. An optional 3/8 inch flare connection site is offered on the 18, 20, and 22 Fr. sizes of the modified device. The 24 Fr. size of the modified device only has a 3/8 inch flare connection site.

The materials used in the two devices are identical. Both use polyvinyl chloride and stainless steel for the spring reinforcement.

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Performance: Comparison studies of the performance of the (modified) Pediatric Venous Return Cannula and the unmodified predicate L Series Pediatric Venous Return Cannula were conducted for pressure drop testing and hemolysis testing. The results of these tests proved the modified device to be substantially equivalent or better than the predicate (unmodified) pediatric venous return cannula. Additional testing was performed on the modified Pediatric Venous Return Cannula to demonstrate current conformance to current market place performance expectations. These tests include:

- Connector attachment
- Clamp test
- Kink test
- Collapse test
- Tensile test
- Simulated use test
- Ship test
- Shelf Life test

These test results showed either no or favorable clinically significant performance differences.

Substantial Equivalence Summary:

In summary, the (modified) TenderFlow™ Pediatric Venous Return Cannula and the predicate (unmodified) L Series Pediatric Venous Return Cannula are substantially equivalent in intended use, principles of operation and technology, design, materials, and performance. Any noted differences between the devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.
- Post-sterilization release for use will be determined in consideration of maximum Ethylene Oxide, Ethylene Chlorohydrin and Ethylene Glycol (as appropriate) residue limits and maximum levels of patient exposure in accordance with EN ISO 10993-7 and AAMI TIR-19.
- Biocompatibility studies were conducted as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993: 2003, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.
- Terumo has conducted material characterization studies – including physio-chemical profiles of aged and non-aged devices to demonstrate stability of the materials, and found the materials to be stable over the expiry of the product.

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Conclusion:

In summary, the TenderFlow™ Pediatric Venous Return Cannula is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the predicate (unmodified) L Series Terumo Pediatric Venous Return Cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

Terumo Cardiovascular Systems Corporation
c/o Ms. Christina L. Thomas
Regulatory Management
6200 Jackson Road
Ann Arbor, MI 48103-9300

Re: K062597
Trade Name: Tenderflow Pediatric Venous Return Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Catheter, Cannula, Tubing
Regulatory Class: II
Product Code: DWF
Dated: October 13, 2006
Received: October 17, 2006

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

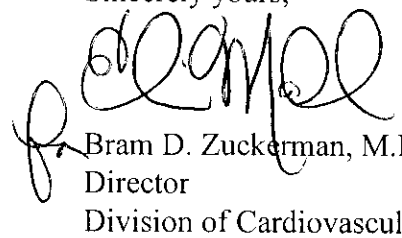
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: TenderFlow™ Pediatric Venous Return Cannula

Indications For Use:

The TenderFlow™ Pediatric Venous Return Cannula is a surgically invasive device intended for short term use and indicated for dual cannulation of the superior and inferior vena cava and single cannulation of the right atrium during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hours of use.

Christina Thomas
Sr. Regulatory Affairs Specialist
Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062597